

Nelson, Bettie L

From: Osborne, Kevin (PMMC Legal)
Sent: Wednesday, April 24, 2002 9:51 AM
To: Solana, Rick P.; Patskan, George J.; Podraza, Ken F.; Elves, Robert G.; Roethig, Hans; Nelson, Bettie L
Cc: Mawyer, Denise T.; Nelson, Bettie L
Subject: RE: 28123-Philip Morris Long Term Study-Draft 4
Sensitivity: Confidential

Another point:

This attachment does not include the Informed Consent, which I understand is to be part of an IRB submission. I suggest you all use the Informed Consent from the last Accord clinical study, modified as necessary to reflect any differences btwn. this last study and the study described in the below protocol.

Pls. fwd. as soon as practical (if needed for the IRB submission) so that we can review and meet the deadline.

Also, what is the "true" deadline for PM comments given that MDS will need to consider and incorporate to meet the May 1 IRB deadline?

thanks

-----Original Message-----

From: Osborne, Kevin (PMMC Legal)
Sent: Monday, April 22, 2002 6:36 PM
To: Solana, Rick P.; Patskan, George J.; Podraza, Ken F.; Elves, Robert G.; Roethig, Hans; Nelson, Bettie L
Cc: Mawyer, Denise T.
Subject: RE: 28123-Philip Morris Long Term Study-Draft 4
Sensitivity: Confidential

Thanks for fwding. I will begin reviewing this evening.

Two initial points:

1. Shouldn't this be discussed w/ Brand, e.g., Tom Garguilo and others, at least as an fyi given that the comparison cigarettes chosen may impact the scope of any potential communication? It would of course be helpful to assess the degree of any potential impact, but the below timing does not permit such an assessment from a legal/regulatory perspective.

2. From a process standpoint, how will we build in time to assess whether revisions suggested by others affect input from a legal/regulatory perspective?

-----Original Message-----

From: Mawyer, Denise T.
Sent: Monday, April 22, 2002 4:34 PM
To: Solana, Rick P.; Osborne, Kevin (PMMC Legal); Patskan, George J.; Podraza, Ken F.; Elves, Robert G.; Roethig, Hans
Cc: Bugg, Joy J.
Subject: FW: 28123-Philip Morris Long Term Study-Draft 4
Sensitivity: Confidential

Dear All -

Attached is the protocol for the long term ACCORD study. Please review and return any comments to Bettie Nelson as soon as you can. The comment/revision process needs to be completed by May 1 to meet the IRB deadline.